

REMARKS

Claims 26-75 are pending. Claims 50-55 and 65-70 have been canceled. Claims 26, 43, 56 and 71 have been amended to recite that the SNRI is not milnacipran. Claim 44 has been amended to correct a typographical error. Claims 26-28, 30, 31, 34-39, 42-46, 49, 56-59, 61-64, and 71-74 have been amended to specify that the SNRI is a “NE \geq 5-HT SNRI.” Claims 76-93 have been added.

Support for the limitation “NE \geq 5-HT SNRI” can be found in the specification at, for example, page 3, lines 12-20 and page 3, line 27 to page 4, line 5.

Support for new claim 76 can be found in the specification at page 3, lines 18-20 and page 11, lines 1-7. Support for new claims 77, 83 can be found in the specification at page 11, lines 5-7. Support for new claims 78, 84 and 90 can be found in the specification at page 11, lines 7-11. Support for new claims 79, 85 and 91 can be found in the specification at page 3, lines 8-9. Support for new claims 80, 86 and 92 can be found in the specification at page 17, lines 15-24. Support for new claims 81, 87 and 93 can be found in the specification at page 14, line 27 to page 15, line 6. Support for new claim 82 can be found in the specification at page 3, lines 21-27 and page 10, line 28 to page 11, line 4. Support for new claim 88 can be found in the specification at page 3, line 28 to page 4, line 5. Support for new claim 89 can be found in the specification at page 11, lines 13-15.

The rejection of claims 50, 52 and 54 under 35 U.S.C. § 102(b)

Claims 50, 52 and 54 have been canceled. Accordingly, this rejection should be withdrawn.

The rejection of claims 26, 28, 29, 32, 33, 35, 39-41, 43, 47, 48, 56, 58, 60, 61, 63, 65, 66, 70, 71, 73, and 75 under 35 U.S.C. § 102(b)

Claims 26, 28, 29, 32, 33, 35, 39-41, 43, 47, 48, 56, 58, 60, 61, 63, 65, 66, 70, 71, 73, and 75 have been rejected under 35 U.S.C. § 102(b) as anticipated by WO 00/32178 (“’178”). The Examiner contends that ‘178 discloses “a method of using a SNRI to treat pain of CFS and FMS using sibutramine” (Office Action, page 2).

'178 does not anticipate these claims because sibutramine is not a SNRI as called for in the present claims. The instant specification defines "SNRI" as a dual serotonin/norepinephrine reuptake inhibitor (specification, page 4, lines 25-28). Sibutramine is a triple reuptake inhibitor, i.e., it inhibits the reuptake of dopamine, serotonin and norepinephrine ('178, page 9, lines 29-31). SNRIs are distinct from triple reuptake inhibitors such as sibutramine, as the instant specification makes clear: "[t]he NE \geq 5-HT compounds can be administered adjunctively with *other* active compounds such as sibutramine" (specification, page 11, lines 5-11; original claim 6). Thus, '178 does not disclose a method of using a SNRI to treat the pain of CFS and FMS as called for in the rejected claims. Accordingly, this rejection should be withdrawn.

The rejection of claims 26, 28-35, 37-43, 45-50, 56, 58-61, 63-66, 68-71, and 73-75 under 35 U.S.C. § 103(a)

Claims 26, 28-35, 37-43, 45-50, 56, 58-61, 63-66, 68-71, and 73-75 have been rejected as obvious over '178 in view of Ninan, Depression Anxiety 2000;12(Suppl 1):90-94 ("Ninan"). According to the Examiner, '178 discloses a method of using a SNRI to treat pain of CFS and FMS using sibutramine, and Ninan discloses a method of using sibutramine [sic] to treat symptoms of fibromyalgia. Further, the Examiner contends that NMDA receptor antagonist properties "would be inherent [in] a compound that yields the instant method;" "it would be obvious to combine another antidepressant, analgesic, muscle relaxant, stimulant, sedative or hypnotic with a SNRI to treat pain or other symptoms of CFS or FMS;" and sustained release formulations are conventional and known in the art (Office Action, page 3). Applicant believes the Examiner has incorrectly identified the compound disclosed in Ninan. The compound in Ninan is venlafaxine, not sibutramine.

As set forth above, sibutramine (the compound disclosed in '178) is not a SNRI, but a triple reuptake inhibitor. See specification, page 4, lines 25-28 (definition of SNRI); '178, page 9, lines 29-31 (sibutramine is a triple reuptake inhibitor); specification, page 11, lines 5-11; original claim 6 (sibutramine belongs to a class of drugs distinct from SNRIs). The references provide no motivation to combine the teachings relating to a different, distinct class of drugs, i.e., triple reuptake inhibitors such as sibutramine, with teachings or knowledge known in the art relating to the claimed dual reuptake inhibitors (SNRIs).

Further, the claims as amended recite that the SNRI inhibits norepinephrine reuptake to an equal or greater extent than it inhibits the reuptake of serotonin (i.e., a “NE ≥5-HT SNRI”). Neither ‘178 nor Ninan discloses or suggests such a compound. ‘178 discloses a triple reuptake inhibitor. Ninan discloses venlafaxine, which is not within the subclass of SNRIs that inhibits norepinephrine reuptake to an equal or greater extent than it inhibits the reuptake of serotonin (see specification, page 4, line 25 to page 5, line 3 and page 8 lines 4-13). Thus, ‘178 and Ninan do not provide any reasonable expectation for the successful use of a NE ≥5-HT SNRI in the methods as claimed.

In view of the foregoing arguments, this rejection should be withdrawn.

The rejection of claims 50-55 under 35 U.S.C. § 103(a)

Claims 50-55 have been canceled. Thus, this rejection has been obviated.

The provisional rejection for obviousness-type double-patenting

This rejection is obviated by the attached Terminal Disclaimer.

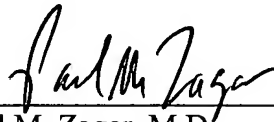
Conclusion

No new matter has been added by these amendments. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: June 10, 2005

By 
Paul M. Zagar, M.D.
Registration No.: 52,392
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 753-6237 (Fax)
Attorneys/Agents For Applicant